EXHIBIT 27

January 30, 2023

RE: Comments on Proposed Changes to the 340B Administrative Dispute Resolution (Docket No. HRSA-2021-000X)

Intermountain Health is a non-profit system in the Mountain West region of the United States and currently has 21 340B hospital covered entities and two 340B grantee covered entities under within its Integrated Delivery Network (IDN). Each of these covered entities has been uniquely impacted by manufacturer overcharging practices. Intermountain Health looks forward to the implementation of ADR process to provide 340B stakeholders with an avenue for fair resolution.

We are writing to provide comments on the Health Resources and Services Administration's (HRSA) notice of proposed rulemaking (NPRM) to revise to the agency's 340B administrative dispute resolution (ADR) process. We submit these comments to express support and concerns regarding the issues addressed below.

I. We support proposed changes that would improve access to the ADR process, limit conflicts of interest, and remove language expanding manufacturer claims beyond those listed in statute.

We appreciate HRSA's proposal to eliminate the $25,000 minimum claim threshold and use of the Federal Rules of Evidence and Federal Rules of Civil Procedure in ADR proceedings. Removing these requirements increases access to the ADR for providers with limited resources.

We support HRSA's proposal to remove Centers for Medicare and Medicaid Services (CMS) staff from ADR panels, as we believe their participation would have created potential conflicts of interest in several areas, such as Medicaid rebates, Medicare reimbursement for 340B drugs, and implementation of the Inflation Reduction Act.

We also support HRSA's proposal to remove language from the 2020 rule stating that manufacturers could bring claims related to a covered entity's eligibility. The statute does not permit the ADR to address eligibility claims, and is strictly limited to diversion, Medicaid duplicate discounts, and overcharges.

II. We request clarification that ADR panels can consider overcharge claims that occur when a manufacturer conditions or refuses sale of a covered outpatient drug at the 340B price.

We urge HRSA to reinstate language that was included in the 2020 final rule making clear that covered entities may bring an overcharge claim in situations where a manufacturer has limited the covered entity's ability to purchase covered outpatient drugs at or below the 340B ceiling price. We also urge HRSA to make clear that a covered entity can bring an overcharge claim related to a manufacturer's refusal to offer 340B pricing and/or establishing conditions that restrict covered entities' access to 340B pricing. When a manufacturer refuses to offer a 340B price for a drug or sets conditions on accessing that price, it necessarily means a covered entity must pay more for the drug than the 340B ceiling price or otherwise incur potentially costly fees to meet the manufacturer's unilaterally imposed conditions, essentially depriving covered entities true access to the statutory price.

Current manufacturer policies cutting off or conditioning access to 340B pricing for contract pharmacy demonstrates that these types of overcharges can have a substantial negative financial impact on covered entities. It is appropriate for an ADR panel to consider these claims because such claims would be based on a violation of a manufacturer's 340B statutory obligations.

III. Suspension of ADR claims would impermissibly limit covered entities' right to challenge illegal manufacturer actions.

We oppose HRSA's proposal to suspend ADR claims that relate to an issue pending in federal court. As demonstrated by the current contract pharmacy litigation, challenges to a government action are not necessarily determined by a single federal court. Claims could be filed in many different federal courts, and each court could reach a different outcome. Suspending a claim because the issue is before a single federal court prevents covered entities from promptly pursuing claims in their own jurisdictions, as they have a right to do under the statute. Since the ADR process is the sole avenue for covered entities to challenge drug companies' unlawful behavior, a significant delay in moving forward with a claim could be devastating for a covered entity and prevent them from making their arguments on how the issue applies to the facts in their situation.

We urge HRSA to revise this provision to allow suspension of a claim only if requested by the covered entity. In that situation, the covered entity is deciding to delay its right to pursue a claim, rather than the government taking that right away. A similar policy is currently in use by the Provider Reimbursement Review Board, a Department of Health and Human Services administrative adjudicative body.

If HRSA moves forward with the policy to suspend claims despite our strong concerns, at the very least HRSA should elaborate on the factors used to determine whether the issues are similar and permit the parties to challenge HRSA's decision to suspend a claim.

IV. To ensure that HRSA's proposed 3-year statute of limitations is fair, we ask the agency to clarify that the time limit for an overcharge claim could begin on a date other than the date of sale under certain circumstances.

Both the proposed rule and current ADR process require claims to be filed within 3 years of the date of an alleged violation. Because the process for determining the ceiling price is confidential and covered entities have no audit rights, there is no way for covered entities to determine whether the price was calculated lawfully.

We urge HRSA to clarify that the 3-year limitation period begins on the date of sale or payment at issue, except in two cases: 1) the manufacturer issues a restatement of the average manufacturer price (AMP), best price, customary prompt pay discounts, nominal prices, or other data that affects the 340B ceiling prices; or 2) the manufacturer should have issued a restatement of any of this data. In the first instance, the 3-year limit should begin on the date that the manufacturer restates the data, and, in the second instance, the 3-year period should begin on the date that the covered entity discovers that the manufacturer should have restated the data. Using a different starting point to begin the 3-year limitation period in these circumstances should not cause any hardship to manufacturers because each manufacturer is required to retain for ten years any records supporting its calculations of AMP, best price, customary prompt payment discounts, and nominal prices.

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Thank you for the opportunity to provide comments.

Sincerely,

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